



THE UNIVERSITY *of* EDINBURGH

## Edinburgh Research Explorer

# Defining the core components of a clinical review of people using Continuous Positive Airway Pressure (CPAP) therapy to treat Obstructive Sleep Apnoea Hypopnoea Syndrome (OSAHS) - An International e-Delphi study

### Citation for published version:

Murphie, P, Little, S, Paton, R, McKinstry, B & Pinnock, H 2018, 'Defining the core components of a clinical review of people using Continuous Positive Airway Pressure (CPAP) therapy to treat Obstructive Sleep Apnoea Hypopnoea Syndrome (OSAHS) - An International e-Delphi study', *Journal of clinical sleep medicine*. <https://doi.org/10.5664/jcsm.7372>

### Digital Object Identifier (DOI):

[10.5664/jcsm.7372](https://doi.org/10.5664/jcsm.7372)

### Link:

[Link to publication record in Edinburgh Research Explorer](#)

### Document Version:

Peer reviewed version

### Published In:

Journal of clinical sleep medicine

### Publisher Rights Statement:

This is the author's peer-reviewed manuscript as accepted for publication.

### General rights

Copyright for the publications made accessible via the Edinburgh Research Explorer is retained by the author(s) and / or other copyright owners and it is a condition of accessing these publications that users recognise and abide by the legal requirements associated with these rights.

### Take down policy

The University of Edinburgh has made every reasonable effort to ensure that Edinburgh Research Explorer content complies with UK legislation. If you believe that the public display of this file breaches copyright please contact [openaccess@ed.ac.uk](mailto:openaccess@ed.ac.uk) providing details, and we will remove access to the work immediately and investigate your claim.



Defining the core components of a clinical review of people using Continuous Positive Airway Pressure (CPAP) therapy to treat Obstructive Sleep Apnoea Hypopnoea Syndrome (OSAHS) - An International e-Delphi study

Phyllis Murphie, RGN, MSc,<sup>1, 2</sup> Stuart Little, MD <sup>1</sup> Robin, Paton BN, <sup>1</sup> Brian McKinstry, MD, PhD, <sup>3</sup> Hilary Pinnock.<sup>2</sup>

1 Allergy and Respiratory Research Group, Usher Institute of Population Health Sciences and Informatics, The University of Edinburgh, UK

2 Department of Respiratory Medicine, NHS Dumfries and Galloway, UK

3 e-Health Research Group, Usher Institute of Population Health Sciences and Informatics, The University of Edinburgh, UK

Corresponding author:

Phyllis Murphie,  
Doorway 3, Medical School, Teviot Place,  
Edinburgh EH8 9AG,  
UK.

Email: [phyllis.murphie@nhs.net](mailto:phyllis.murphie@nhs.net)

Institution where work was performed: Allergy and Respiratory Research Group, Usher Institute of Population Health Sciences and Informatics, The University of Edinburgh.

All authors have seen and approved the manuscript.

The authors disclose receipt of the following financial support for the research, authorship and/or publication of this article: The Scottish Association of Sleep Apnea SASA have provided financial support towards tuition fees for PM for academic year 2017-2018. NHS Dumfries and Galloway have provided support for tuition fees for PM for academic year 2017-2018.

The authors declare no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

Number of tables: 4

Number of figures: 1

Number of appendices: 3

Abstract word count: 200

Manuscript word count: 2935

Brief Summary: Current Sleep medicine guidelines recommend regular review in CPAP users with OSAHS. However they do not collectively define the core components and frequency of such a review. We aimed to achieve consensus on essential components and frequency of review.

Study Impact: This is the first study to provide an international consensus on the most important components that may be considered when reviewing people using CPAP therapy. Our findings may inform future guideline recommendations for reviewing CPAP users.

## **Abstract**

**Study Objectives:** Guidelines recommend regular review in CPAP users with Obstructive Sleep Apnoea Hypopnoea Syndrome (OSAHS) but do not agree on core components and frequency. We aimed to achieve consensus on essential components and frequency of review.

**Methods:** We employed an e-Delphi approach, recruiting a multidisciplinary international expert panel to identify components based on a list compiled from guidelines and to score these on a scale 1-5 over three rounds. Consensus was defined as  $\geq 75\%$  agreement for scores of  $\geq 4$ . Free text comments were thematically analysed.

**Results:** Forty participants completed three rounds scoring 36 potential components. Seventeen components achieved consensus: treatment acceptability, sleep quality, symptom resolution (including reduction in apnoea-hypopnoea index), assessment of sleepiness (including when driving), technical CPAP issues (mask fit/humidification/cleaning/filters), recording CPAP adherence and quality of life. Participants suggested 12-18 monthly reviews (more frequent when commencing CPAP) or 'on demand'. Free-text comments highlighted that reviews should be multidisciplinary, flexible (including telehealth) and focus on symptom control.

**Conclusion:** We mapped 17 prioritised components to a suggested template that may support clinical reviews. Reviews should be flexible, frequent in early stages shifting to 'on-demand' and/or remote follow-up for maintenance. Our findings may inform future guideline recommendations for reviewing CPAP users.

**Keywords:** sleep apnoea, OSAHS, CPAP, routine review

## Background

Obstructive Sleep Apnoea Hypopnoea (OSAHS) is a very common; treatable condition that represents a major public health issue globally and is an important cause of morbidity and mortality.<sup>1-8</sup> It has been recognised as an important respiratory condition for more than 36 years since the groundbreaking publication by Sullivan et al in the Lancet in 1981.<sup>9</sup> OSAHS is usually a lifelong condition which requires long-term treatment such as Continuous Positive Airway Pressure (CPAP) in order to relieve symptoms, improve quality of life, mitigate the impact of daytime sleepiness on work-performance and driving related accidents, and reduce the risk of cardiovascular co-morbidity.<sup>1, 10-12</sup>

Current guidelines recommend regular review for CPAP therapy users and suggest a range of components that could be included such as assessment of subjective daytime sleepiness using the validated Epworth Sleep Scale, adherence to CPAP, practical issues with masks and equipment, guidance on driving license advice and weight and blood pressure monitoring. However the guidelines give conflicting advice about the core contents of a clinical review (see Table 1) and how often this should take place and there is therefore a need for consensus.

An e-Delphi is a method that can be used for reaching consensus among a panel of experts where there is limited evidence on the priority attached to a range of items.<sup>13,14</sup> Communication can take place by email, enabling participation by national and international participants over a short time-frame.<sup>14</sup> We conducted an international e-Delphi study to reach consensus on the important core components and optimal frequency of a clinical review in people using CPAP therapy for OSAHS.

## **Methods**

### **Ethics**

We obtained ethical approval from the Usher Institute of Population Health Sciences and Informatics, University of Edinburgh (application number 1700).

### **e-Delphi methodology**

Stemming from the RAND Corporation in the 1950s,<sup>15</sup> an e-Delphi delivers a series of questionnaires over (typically) three rounds in which expert panellists contribute their ideas independently and anonymously. In subsequent rounds individual responses may be influenced by feedback of the collective participant responses from previous rounds facilitating consensus.

### **Guideline review and pilot work**

We identified current guidelines, position statements, best practice statements/ recommendations and consensus statements for the management of adults with OSAHS therapy, searching Medline, Turning Research Into Practice (TRIP) databases and Google Scholar using the following search terms '*sleep apnoea/apnea syndrome*', '*CPAP therapy*', '*national/international guidelines*' '*clinical review*' and '*follow up*'. We scrutinised these documents for recommendations about the content of regular review of CPAP users and extracted all suggested elements of a review to form an initial list of possible components. We then piloted the e-Delphi process with ten local sleep medicine clinicians who were asked to 'sense-check' the review components from the literature review; any additional components they considered to be important would be added to the initial list.

### **Recruitment of an expert panel**

Delphi panels are generally fewer than 50 participants; and the majority of Delphi studies have included between 20-30 respondents.<sup>14</sup> We therefore invited, by e-mail, 80 international experts with a view to recruiting about 30 participants to the study. The clinicians who were involved in the pilot work were excluded from the expert panel. Our recruitment strategy was to invite healthcare professionals who were actively involved in the review of people with OSAHS who were using CPAP therapy (e.g. clinical academics, respiratory physicians, general practitioners, clinical nurse specialists/nurse practitioners, respiratory therapists and respiratory physiologists (healthcare scientists trained to support people using CPAP)). We also invited up to five individuals with OSAHS using CPAP from a local service. Our aim was to encompass both clinical experiences with relevant academic expertise as well as CPAP therapy users. All suggestions, comments and data were anonymised but participants were offered the option of being acknowledged in publications.

### **The three rounds of the e-Delphi:**

We followed recommended consensus methodology,<sup>13, 15</sup> and anticipated that it would require up to three rounds to reach consensus with a fourth round if required. The data collection sheets for the three rounds are in Appendix 1.

### **Round 1: Open round - to compile a list for prioritisation of components of a clinical review in CPAP users.**

Initially we developed a data collection sheet (using an Excel spreadsheet) of potential clinical review components from our literature review of current guidelines combining any additional suggestions from our pilot work. The Round 1 data collection sheet was then emailed to the expert panel requesting any additional review components and/or free text comments on the existing suggestions. Opinions were also sought regarding the importance of the timing and

suggested frequency of clinical review. We collated all the additional suggested components to create the final list for prioritisation in Round 2.

### **Round 2: First scoring round**

This was the first scoring round and the panel were asked to review the list generated from the free-text round and identify the components that should be prioritised in a review using a scale of 1-5 (1 = unimportant and 5 = very important). (We avoided ranking as the importance of specific prioritised components would depend on individual clinical context). The results were collated and a median score calculated for each component in preparation for Round 3.

### **Round 3: Second scoring round**

The Round 3 data collection sheet included the median scores from Round 2 along with individuals' own Round 2 score. In Round 3 the participants were given the opportunity to revise their opinions (or not) on the priority of the clinical review components in the light of the median findings of the previous round by again ranking each research question on a score of 1 to 5 (where 1 = unimportant and 5 = very important). We predicted an acceptable level of agreement on priority components with three rounds however a final fourth round (following the method of the Round 3) could be conducted if required.

### **Analysis**

We calculated the median scores for each component of the clinical review and the proportion of respondents scoring each item as 4 or 5. In discussion with the multidisciplinary team, consensus was defined as  $\geq 75\%$  agreement for the priority scores of 4 or 5. Prioritised components were grouped (e.g. treatment acceptability; technical CPAP issues; sleepiness assessment; adherence;



symptom resolution; assessing sleep quality; driving issues; quality of life; lifestyle issues/sleep hygiene) and mapped to a template which could be used to facilitate a standardised review.

### **Free text comments from participants**

Participants were invited to contribute their additional free text comments in all the rounds. We used an inductive approach to thematically analyse the free text comments to identify the key issues from the perspective of the individual participants. The free text comments from individual participants were not shared with the panel members

## **Results**

### **Literature review and preparation of the initial list**

The literature review identified 13 national/international guidelines, best practice position or consensus statements that made recommendations on the long-term management and follow up of CPAP therapy users (see Table 1 for a summary of the recommended components). From the literature review an initial list of 12 review components was compiled. No additional components were suggested by the ten local sleep medicine clinicians who piloted the process.

### **International expert panel**

Of the 80 potential participants approached, 47 consented to participate from 21 countries (Europe n=37, Australasia n=5, Asia n=3, North America n=2). Professionals (some represented more than one group) encompassed respiratory physicians (n=29), academics (n=25), journal editors (n=9), specialist respiratory nurses (n=5), respiratory physiologists (n=3), respiratory therapists (n=1), and CPAP therapy users (n=6) (Table 2). 44 completed round 1; 41 and 40 participants completed rounds 2 and 3 respectively. The four withdrawals were all respiratory physicians.

### **Final list of components for scoring**

An additional 24 components were suggested in the free-text round and included in the list for the scoring rounds making a total of 36 components.

### **Components reaching consensus threshold**

17 components achieved a priority consensus of  $\geq 75\%$  indicating agreement that these components were important to include in a clinical review. Table 2 shows the percentage consensus for all 36 components at the end of Round 3, listed in order of percentage agreement with the priority scores.

### **Themes emerging from the free-text comments:**

Table 3 gives illustrative quotes from the free-text comments providing contextual support for the rating decisions and highlighting some practical approaches to mode of delivery.

### **Frequency of review**

Figure 1 shows responses on frequency and mode of review. Frequent review (face to face or telephone) was considered important to support initiation of CPAP following diagnosis and in the early months of use. Opinions on the frequency of review once CPAP was established was more varied with the majority of participants suggesting twelve to eighteen-month follow up, and more frequent reviews targeted on those with poor adherence. A flexible approach that offered 'open access or follow up 'on demand' was prioritised by 80% of participants. Nearly half the respondents highlighted contexts (such as a specific request from a traffic agency, or before elective surgery) which might determine the need for a review. Follow up via a telemonitoring option, where available, was acceptable. There was general agreement that the timing of the review should be flexible to meet the clinical and support needs of the patient as well as being compatible within the healthcare delivery context.

## **Discussion**

### **Main findings**

This is the first study to provide an international consensus on the most important components that should be considered when reviewing people using CPAP therapy. From a list of 36 components, 17 reached consensus ( $\geq 75\%$ ) and were considered the most important to include during a CPAP therapy review. The components identified have been grouped into key categories: Technical aspects (n=8 components); General medical assessment (n=7); Sleepiness assessment (n=3); Symptom resolution (n=3); Acceptability of treatment (n=2); Adherence check (n=2); Assessing sleep quality (n=2); Driving issues (n=2); Quality of life (n=2); and Lifestyle issues/sleep hygiene (n=2). The need for flexible follow up arrangements was highlighted by the free text comments indicating that clinical review arrangements should focus on individual patient needs.

### **Interpretation in the light of other literature**

Current clinical guidelines regarding the review of CPAP users collectively suggest ten components that should be included in a CPAP review with the guideline from the American Academy of Sleep Physicians being the most comprehensive and identifying eight of twelve prioritised components.

<sup>17</sup> There is however wide variation in the guideline recommendations published between 2003 <sup>16</sup> to 2016 <sup>26</sup>, highlighting the need for an international consensus on what is important to include in a clinical review and how often this should occur.

Some components (e.g. asking if any problems with sleepiness while driving, subjective assessment of sleepiness e.g. Epworth Sleepiness Scale, checking for any mask interphase issues) were strongly prioritised in our e-Delphi study but were not always recommended by the guidelines. Specifically, current guidelines do not highlight checking the Apnoea Hypopnoea Index

(AHI) in the downloaded CPAP data despite the priority accorded by most e-Delphi participants to assessing improvements in AHI. In the United Kingdom, this priority may reflect the recently updated guidance from the Driving and Vehicle Licensing Agency which states that in moderate to severe OSAHS subsequent licensing will require; control of the condition; improved sleepiness and treatment adherence.<sup>27</sup> This is an important finding of our e-Delphi study and driving-related issues need to be given a higher priority in future clinical review and guideline development.

Our study identified a number of components that were considered as being less important (<75%) suggesting these may be optional and included according to clinical judgement (Table 2). For example, 'asking about co-morbidities' which achieved a rating just under the priority threshold will be important in some clinical contexts. Ongoing/long term review also provides the opportunity for education /support and reinforcement of treatment rationale in CPAP users.

Asking about quality and quantity of sleep, sleep routine times and work schedules/shift patterns, measuring patients' quality of life, and reviewing patients' preparedness to continue with treatment, all reached a priority consensus of >75% although few current guidelines specifically recommend these components. The consensus gained from our e-Delphi study has highlighted the importance of considering including these components in a review. The priority attached to checking practical maintenance of CPAP equipment depended on the organisation of sleep medicine services; in some systems this was not part of a clinical review.

One option for implementing these clinical review components in CPAP users is to provide a clinical review template. While opinions vary on the use of templates in clinical practice, they can facilitate a structured process and improve consistency of care.<sup>28</sup> However there are limitations to the use of clinical templates; for example they may not address all issues with CPAP usage from a patient's perspective so some flexibility in their use is important. Building on our findings we

have outlined a suggested clinic review template based on the components prioritised by the e-Delphi respondents that could assist sleep medicine clinicians to provide a structured review (see table 4).

A key finding from our e-Delphi study is that there needs to be flexibility in the delivery of services – both in frequency and mode. Early and frequent review is recommended as a priority for new CPAP users and those having difficulty with adherence, or practical problems such as treatment side effects, and then reducing to annual/ biannual review when stable. The option of offering an ‘open access’ service in which the patient could determine their need for review appealed to 80% of the respondents in our study. With the ever increasing demand for sleep medicine services globally this may be seen as an attractive option for healthcare providers however there is currently no published literature to inform this practice. Furthermore, with the rise in the implementation of sleep telemedicine services CPAP review can be facilitated with telemonitoring and overseen remotely.

### **Strengths and limitations**

We generated an extensive list of potential components of a CPAP therapy clinical review by amalgamating recommendations from current guidelines, best practice and position statements with suggestions from an international multidisciplinary panel of participants of clinicians/academics involved in this field and also CPAP therapy users. Interpretation and development of the outline review template followed a structured mapping of components. Forty participants (exceeding our recruitment target) completed all three rounds of our study electronically; only one person withdrew between the two scoring rounds enabling the consensus process. An important strength of our study is that the participants were from a range of healthcare backgrounds involved in the delivery of sleep medicine services, representing 21

countries with a broad range of economic backgrounds and healthcare systems. Although the number of participants recruited to our expert panel is larger than other e-Delphi studies<sup>23, 24</sup> they may not represent the full range of perspectives from sleep medicine clinicians/providers as the delivery of sleep medicine services varies widely in healthcare systems globally. Providing an initial list of components derived systematically from guidelines would have helped clarify the process for participants but will have influenced their suggestions, though the international expert panel of clinicians/academics and CPAP therapy users trebled the list of components. A consensus conference would have allowed a nuanced discussion but, for logistical reasons, would have restricted the number of participants, in particular reducing the international perspective. However, our e-Delphi actively encouraged free text comments throughout all rounds of the study which we analysed thematically to provide insights into the results of scoring.

## **Conclusion**

Our international expert panel agreed that the most important components of a clinical review of people using CPAP therapy to treat OSAHS were assessing: treatment acceptability; technical aspects of therapy; objective sleepiness assessment; recording adherence/efficacy verbally or by data download via memory card/remote monitoring; symptom resolution; driving issues; sleep quality; quality of life and lifestyle issues/sleep hygiene. We have mapped these components into a suggested sleep medicine review template which may assist clinicians to conduct a patient centred, structured and evidence-based clinical review. There were diverse opinions on the optimal frequency of review but general agreement that relatively frequent review should be undertaken in the newly diagnosed patient. Long term follow up will be less frequent, or potentially 'on demand', and can be provided by a range of professionals with the option of using telemonitoring where available. Feedback on the utility of the template is welcomed, so that our findings can be refined to inform future guideline recommendations and the delivery of care for people with OSAHS using CPAP.

## **Abbreviations**

AHI	Apnoea Hypopnoea Index
CPAP	Continuous Positive Airway Pressure
e-Delphi	Electronic Delphi
n	Number
OSAHS	Obstructive Sleep Apnoea Hypopnoea Syndrome

**Acknowledgements:** The authors thank NHS Dumfries and Galloway for granting study time to PM to undertake this e-Delphi study. They are also grateful to the Scottish Association of Sleep Apnoea) awarding a research scholarship to PM in 2014–2015. We also acknowledge the contribution of the following members of the expert panel: William Anderson, Ferran Barbe, James Boyd, Marie Bruyneel, Catherine Buchan, Christopher Carlin, David Comer, Frankie Clavaud, Wendy Douglas, Mark Elliott, Francesca Fanfulla, Patrick Fitch, Jan Hedner, Mark Howard, Juan Fernando Masa Jimenez, Julian Leggett, Pei Lin Lee, Eric Livingston, Claudia Maldonado, Tom MacKay, Ralston McKay, Belinda Miller, Mark Miller, Matt Naughton, Georg Nilus, Jean-Louis Pepin, Alex Perkins, Victor Rolando, Silke Ryan, Chamara Senaratna, Stuart Schembri, Robin Smith, Gail Spacic, Patrick Strollo, Chris Turnbull, Johan Verbraeken, Michele Vitacca, Marija Vukoja, Liz Walker, Kim Ward.

**Contributorship:** The following author contributions were made: conceived and designed the e-Delphi; PM, SL, BMcK and HP; performed the e-Delphi: PM with SL, BMcK and HP; analysed the data: PM, SL, BMcK and HP; wrote the paper: PM, SL, RP, BMcK and PM and HP are guarantors.



## References

1. British Thoracic Society. BTS position statement driving and Sleep apnoea. BTS 2014. Available from <https://www.brit-thoracic.org.uk/...bts/.../position-statement-on-driving-and-obstructiv>. (Accessed June 2016).
2. European Lung Whitebook: Sleep breathing disorders. Available from [www.erswhitebook.org/chapters/sleep-breathing-disorders/](http://www.erswhitebook.org/chapters/sleep-breathing-disorders/). (Accessed June 2016).
3. Fox N, Hirsch-Allen A, Goodfellow E et al. The impact of a telemedicine monitoring system on positive airway pressure adherence in patients with obstructive sleep apnea: a randomized controlled trial. *Sleep*. 2012;35(4):477-481.
4. Punjabi NM. The epidemiology of adult obstructive sleep apnea. *Proc Am Thorac Soc*. 2008;5(2):136-143.
5. Lee W, Nagubadi S, Kryger M, et al. Epidemiology of Obstructive Sleep Apnea: a Population-based Perspective. *Expert Rev Respir Med*. 2008;2(3):349-364.
6. Isetta V, Negrín M, Monasterio C, et al. A Bayesian cost-effectiveness analysis of a telemedicine-based strategy for the management of sleep apnoea: a multicentre randomised controlled trial. *Thorax*. 2015;70(11):1054–1061.
7. Ellen R, Marshall S, Palayew M, et al. Systematic review of motor vehicle crash risk in persons with sleep apnea. *J Clin Sleep Med*. 2006; 2(2):193-200.
8. Heatley E, Harris M, Battersby M, et al. Obstructive sleep apnoea in adults: a common chronic condition in need of a comprehensive chronic condition management approach. *Sleep Med Rev*. 2013;17(5):349-355.
9. Sullivan C, Issa F, Berthon-Jones M, et al. Reversal of obstructive sleep apnoea by continuous positive airway pressure applied through the nares. *Lancet*. 1981;1(8225):862-865.
10. Adult obstructive sleep apnea task force of the american academy of sleep medicine. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *J Clinl Sleep Med*. 2009;5(3):263-276.
11. BMJ Best Practice - Obstructive sleep apnoea in adults. 2016. <http://bestpractice.bmj.com/topics/en-gb/215/guidelines>. Accessed 05/03/18.
12. NICE Guidelines - Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome. Published March 2008. Available from <https://www.nice.org.uk/guidance/ta139>. Accessed 05/03/18.

13. Hsu C, Sandford B. The Delphi technique: making sense of consensus. *Practical Assessment, Research & Evaluation*. 2007;12(10):1-8.
14. Avella J. Delphi panels: Research design, procedures, advantages, and challenges. *Int J Docl Studies*. 2016; 11: 305-321.
15. Fink A, Kosecoff J, Chassin M, et al. Consensus methods: characteristics and guidelines for use. *Am J Pub Health*. 1984;74(9):979-983.
16. Scottish Intercollegiate Guideline Network SIGN - Management of obstructive sleep apnoea/hypopnoea syndrome in adults - A national clinical guideline. 2003. Available from <https://www.nice.org.uk/guidance/ta139/chapter/1-guidance>
17. Epstein L, Christo D, Strollo P et al. Clinical guideline for the management and long-term care of obstructive sleep apnoea in adults. *J Clin Sleep Med*. 2009;5(3):263-276.
18. Australasian Sleep Society. Position Paper - Best Practice Guidelines for Provision of CPAP Therapy. 1 – 22. Available from <https://www.sleep.org.au/documents/item/66>. Updated 2009. Accessed 05/03/18
19. Lloberes P, Durán-Cantolla J, Martínez-García MÁ, et al. Diagnosis and treatment of sleep apnea-hypopnea syndrome. *Archivos de Bronconeumología* (English Edition). 2011; 47(3):143-156.
20. Fleetham J, Ayas N, Bradley D, et al. Canadian Thoracic Society 2011 guideline update: Diagnosis and treatment of sleep disordered breathing. *Can Resp J*. 2011;18(1):25-47.
21. Qaseem A, Holty J, Owens D, et al. Management of obstructive sleep apnea in adults: A clinical practice guideline from the American College of Physicians. *Ann Intern Med*. 2013;159(7):471-483.
22. Sharma S, Katoh V, Mohan A, et al. Consensus and evidence-based Indian initiative on obstructive sleep apnea guidelines 2014 (first edition). *Lung India: official organisation of Indian Chest Society*. 2015;32(4):422-434.
23. Korpershoek Y, Bruins S, Effing T, et al. Self-management behaviors to reduce exacerbation impact in COPD patients: a Delphi study. *Int J Chronic Obstructive Pulmonary Disease*. 2017;12:2735-2746.
24. Pinnock H, Østrem A, Rodriguez M, et al. Prioritising the respiratory research needs of primary care: the International Primary Care Respiratory Group (IPCRG) e-Delphi exercise. *Prim Care Respir J*. 2012; 21(1):19-27.

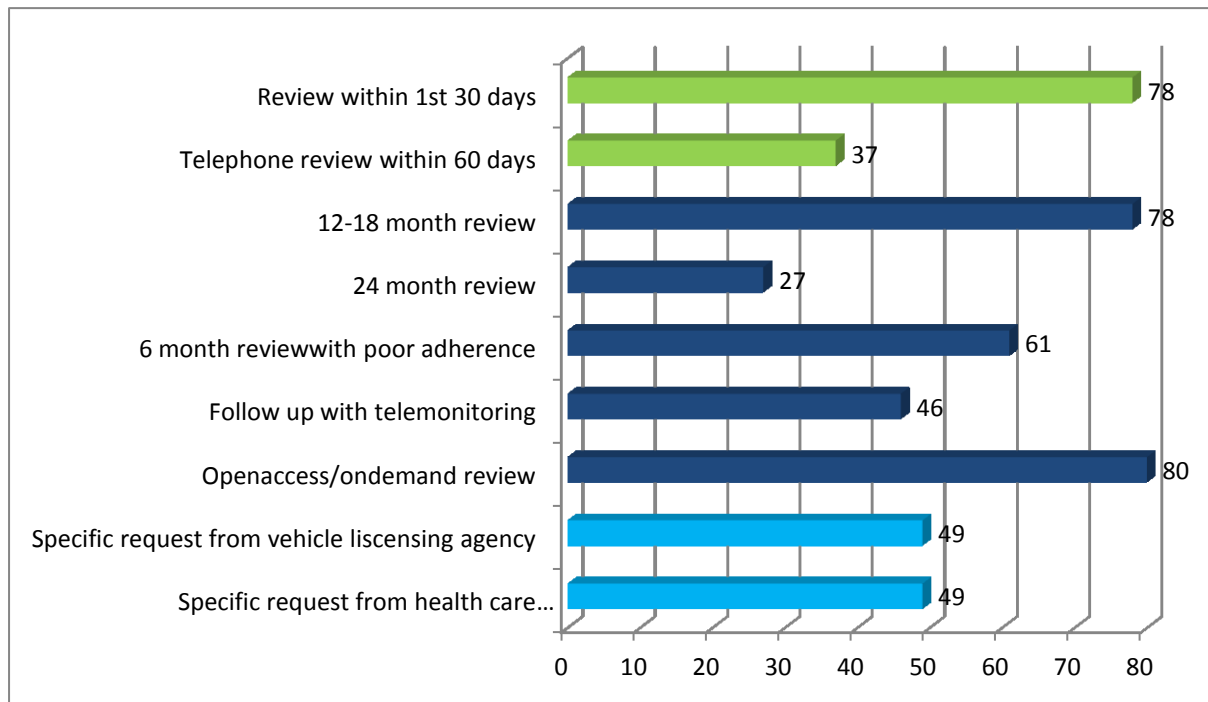
25. Tsara V, Amfilochiou, A. et al. Guidelines for diagnosing and treating sleep related breathing disorders in adults and children (Part 2: Treatment). *Hippocratia*. 2009; 13(4):247-252.
26. Netzer N , Ancoli-Israel S , Bliwise D, et al. Principles of practice parameters for the treatment of sleep disordered breathing in the elderly and frail elderly: the consensus of the International geriatric sleep medicine task force. *Eur Resp J*. 2016 Oct; 48(4):992-1018. doi: 10.1183/13993003.01975-2015. Epub 2016 Jul 28.
27. Driver and Vehicle Licensing Agency. 2017. Advice for medical professionals to follow when assessing drivers with miscellaneous conditions. <https://www.gov.uk/guidance/miscellaneous-conditions-assessing-fitness-to-drive#excessive-sleepiness--including-obstructive-sleep-apnoea-syndrome>. Date last updated 11/03/16. Accessed 04/12/17.
28. Billiones, R. 2014. Document templates for medical writers. *Medical writing*. 23(1):17-21. <https://doi.org/10.1179/2047480613Z.000000000189>. Accessed 5/03/18.

**Table 1 - Components of a routine review recommended by current guidelines on the management of OSAHS**

<b>Guideline body, date</b> <sup>[ref]</sup> :	Weight monitoring	BP monitoring	Objective measure of Sleepiness	Reported symptoms	CPAP adherence	Mask interphase issues	Pressure setting/ comfort	Reported side effects	Chest auscultation	CPAP issues /safety check	Driving/DVLA guidance	Follow up
Scottish Intercollegiate Guideline Network, 2003 <sup>(16)</sup>												
National Institute for Health and Clinical Excellence 2008 updated 2015 <sup>(12)</sup>	✓	✓			✓							✓
Improving and Integrating Respiratory Services 2009 <sup>(1)</sup>				✓	✓			✓		✓	✓	✓
American Academy of Sleep Medicine 2009 <sup>(17)</sup>	✓		✓	✓	✓	✓	✓	✓		✓	✓	✓
Australasian Sleep Association 2009 <sup>(18)</sup>				✓	✓	✓		✓		✓		✓
Hellenic Society of Sleep Disorders 2009 <sup>(25)</sup>			✓			✓	✓			✓		✓
Spanish Pulmonology Society 2011 <sup>(19)</sup>	✓			✓	✓							✓
Canadian Thoracic Society 2011 <sup>(20)</sup>												
BMJ Best practice 2016 <sup>(11)</sup>				✓	✓							
American College of Physicians 2014 <sup>(21)</sup>	✓		✓		✓							
European Respiratory Society White book 2014 <sup>(2)</sup>												✓
India Institute of Medical Sciences 2015 <sup>(22)</sup>												
International Geriatric Sleep Medicine task force 2016. <sup>(26)</sup>												

**Figure 1 - Frequency of review expressed as percentage of respondents**

■ = early review    ■ = longer term review    ■ = specific request for review



**Table 2- Components of a clinical review, listed in percentage order of proportion of respondents who gave priority score of 4 or 5**

Components of a clinical review, listed in order of proportion of respondents who gave priority score of 4 or 5	% agreement with priority scores	Grouped into key categories
Components achieving the priority threshold for consensus (75% agreement with the priority score)		
Checking for treatment side effects	98	Acceptability
Checking mask fit issues	98	Technical
Recording objective assessment of sleepiness/ somnolence e.g. Epworth Sleep Score	95	Sleepiness assessment
Recording of CPAP adherence/efficacy by data download via memory card/remote monitoring	95	Adherence check
Ask if any problems with sleepiness while driving	95	Sleepiness assessment
Checking if initial symptoms for referral have improved e.g. tiredness/sleepiness/hypersomnolence/concentration /memory	93	Symptom resolution
Checking patient quality of sleep /feeling refreshed on waking	90	Assess sleep quality
Ensuring CPAP is resolving the Apnoea Hypopnoea Index (AHI)	90	Symptom resolution
Asking about quality/quantity of sleep/sleep routine times	88	Assess sleep quality
Patients preparedness to continue with treatment	88	Acceptability
Asking about current driving status - Car/Heavy goods Vehicle license	85	Driving
Checking patient quality of life	83	Quality of life
Verbally asking about CPAP adherence/Sleep time	80	Adherence check
Requirement for humidification	78	Technical
Frequency of cleaning mask interface and circuit/changing filters	78	Technical
Check for control of witnessed residual snoring or apnoeas, choking spells	76	Symptom resolution
Asking about work schedule/Shift Pattern	76	Lifestyle issues/seep hygiene
Components not achieving the priority threshold for consensus, but with >50% agreement with priority scores		
Review of medical history, medication, any new co morbidities in relation to symptoms/need for hospitalisation	73	General medical assessment
Ask about factors that help/hinder CPAP use	73	Technical
Checking body weight	71	General medical assessment

Support system at home (Help with mask on/off fitting and filling of humidifier if used) /partner engagement	65	Technical
Recording the altitude where the patient lives and the altitude where the sleep study was carried out	61	Technical
Checking that any relevant Vehicle Licensing agencies are aware of the condition	60	Driving
Requirement to repeat diagnostic study with significant weight loss/weight gain	60	General medical assessment
Components with <50% agreement with priority scores		
Checking partner feedback / quality of life	48	Quality of Life
Fatigue and depression scale /as interfering with objective assessment of sleepiness e.g. epworth sleep score	43	Sleepiness assessment
Checking electrical safety of CPAP unit	33	Technical
Nocturia/Frequency of getting up to pass urine	33	General medical assessment
Examination of the nasal passage and throat	28	General medical assessment
Advice re air travel	25	Lifestyle issues/seep hygiene
CPAP unit noise level	25	Technical
Cognitive/developmental issues	23	General medical assessment
Chest Auscultation	0	General medical assessment

**Table 3 – Themes from free text comments**

Assessment of symptom resolution
<p><i>“Assessment should be focussed on whether CPAP has improved the symptoms responsible for initial presentation as CPAP is mainly a treatment for symptoms” (Respiratory Physician and Academic).</i></p> <p><i>“Should also have some documentation of residual AHI on treatment although I am cautious of putting this in as it is often a software derived number and in a significant number of cases never fully settles to &lt;5.” (Respiratory Physician).</i></p>
Assessment of sleepiness and its impact on activities including driving
<p><i>“Questioning whether CPAP is used for all sleep episodes, daytime napping etc, and documentation of whether excessive sleepiness has improved” (Respiratory Physician).</i></p> <p><i>“I would take a detailed sleep history for a patient with residual sleepiness despite apparently effective CPAP”. (Respiratory Physiologist).</i></p> <p><i>“Professional drivers should have annual nurse review at least”. (Respiratory Physician).</i></p> <p><i>“We tend to offer 12 monthly reviews for HGV drivers”. (Specialist Nurse).</i></p> <p><i>“Professional drivers will continue to be seen yearly”. (Respiratory Nurse Specialist).</i></p>
The importance of monitoring adherence to CPAP therapy
<p><i>“Telemedicine for CPAP adherence tracking should be encouraged and reimbursed” (Respiratory Physician).</i></p> <p><i>“Download of the CPAP device should be performed or supplied ahead by the supplier” (Respiratory Physician).</i></p>
Technical issues regarding CPAP therapy
<p><i>“Checking the operational status and cleanliness of the CPAP humidifier and mask. Need for replacement of same”. (Respiratory Physician).</i></p> <p><i>“Some of the content of CPAP reviews, such as electrical safety testing will also depend on whether the machine is provided by the CPAP clinic, rented or purchased by the patient” (Respiratory Physician).</i></p>
Checking partner feedback and quality of life
<p><i>“Clinical review that incorporates the patient’s bed-partner and/or other close family may be useful to help identify and manage any potential problems”. (Specialist Nurse).</i></p>
The requirement for general medical assessment
<p><i>“Requirement to repeat CPAP titration study or conduct a review if the download information or patient report is inconsistent helps with mask issues CPAP pressure etc”. (Respiratory Physician).</i></p>
Frequency and mode of review
<p><i>“An early review after the first visit to initiate CPAP is in my view crucial for increasing the chance of long term CPAP compliance.” (Respiratory Physician).</i></p> <p><i>“The frequency of a clinical review varies globally depending on local health care systems and providers, and professional drivers should have annual review.”</i></p> <p><i>“Clinical review provides the opportunity for education/support and reinforcement of treatment “. (Respiratory Nurse Specialist).</i></p>



**Table 4 - Outline of a Sleep Clinic Review Template**


Acceptability of treatment
Checking for treatment side effects Preparedness to continue with treatment
Technical aspects of therapy
Checking mask fit issues Requirement for humidification Frequency of cleaning mask interface and circuit/changing filters
Objective assessment of sleepiness
Recording objective assessment of sleepiness/ somnolence e.g. Epworth Sleep Score Ask if any problems with sleepiness while driving
Measurement of adherence to CPAP therapy
Recording of CPAP adherence/efficacy by data download via memory card or remote monitoring Verbally asking about CPAP adherence/Sleep time
Resolution of symptoms
Checking if initial symptoms for referral have improved e.g. tiredness, sleepiness, hypersomnolence, concentration, memory Ensuring CPAP is resolving the Apnoea Hypopnoea Index Check for control of witnessed residual snoring or apnoeas, choking spells
Assessing sleep quality
Checking patient quality of sleep /feeling refreshed on waking Asking about quality/quantity of sleep/sleep routine time
Driving/Vehicle licensing agency issues
Asking about current driving status - Car/Heavy goods Vehicle license
Quality of Life
Checking patient quality of life
Lifestyle issues/Sleep hygiene
Asking about work schedule/Shift Pattern

Note: This table lists the prioritised components of a review. The vision is that this might be used as the basis of a (potentially computerised) template which would:


- Start with an open question setting the agenda for the review (What does the patient wish to discuss?)
- Act as a 'checklist' to prompt delivery of important components of a review
- Include space for free-text entries
- Be followed by a second page with the components that did not reach consensus, but which will be important in some contexts

### Appendix 1 - Round 1, 2 and 3 data collection sheets.

[illegible]

 <b>Round 2 - An International e-Delphi exercise to define the components of a clinical review of people using CPAP therapy</b>		Participant ID
<p>There are three parts to this round of the study: (1) Scoring the importance of the components of a CPAP review, (2) specification of timing/frequency of CPAP review, and (3) opportunity to provide free text comments. We request that you complete sections 1 and 2 as a minimum.</p>		
<p>Thank you for agreeing to help with this e-Delphi exercise. <b>This is round 2.</b>  Listed below are the possible components of a clinical review of a patient using CPAP therapy.  We now invite you to score the importance of the components listed below with 0 being unimportant and 5 being very important</p>		
Clinical CPAP review	We estimate it will take up to 15 mins to complete the round 2 questionnaire.	
Important!	Save this spreadsheet to your desktop, or a folder on your computer. If you don't do this you will lose all your responses when you close the spreadsheet	
<p><b>Section 1. Consists of components of a CPAP clinic review generated from round 1 of the e-Delphi study. Please specify the importance of these with 0 = unimportant and 5 = very important.</b></p>		
Component of the CPAP review	Score	
Recording Epworth Sleep Score		
Verbally asking about CPAP adherence/Sleep time		
Recording of CPAP adherence/efficacy by data download via memory card/remote monitoring		
Checking mask fit issues		
Chest auscultation		
Checking for treatment side effects		
Checking electrical safety of CPAP unit		
Checking body weight		
Checking blood pressure		
Asking about current driving status - Car/Heavy goods Vehicle license		
Checking that any relevant Vehicle Licensing agencies are aware of the condition		
Review of medical history, medication, any new co morbidities in relation to symptoms/need for hospitalisation		
Checking partner feedback / quality of life		
Checking patient quality of life		
Checking patient physical activity/exercise		
Checking patient quality of sleep /feeling refreshed on waking		
Asking about quality/quantity of sleep/sleep routine times		
Asking about work schedule/Shift Pattern		
Ask if any problems with sleepiness while driving		
Checking if initial symptoms for referral have improved e.g. tiredness/sleepiness/hypersomnolence/ concentration/memory		
Patients preparedness to continue with treatment		
Check for control of witnessed residual snoring or apnoeas, choking spells		
Recording the altitude where the patient lives and the altitude where the sleep study was carried out		
Cognitive/developmental issues		
Support system at home (Help with mask on/off fitting and filling of humidifier if used) /partner engagement		
Examination of the nasal passage and throat		
Ensuring CPAP is resolving Apnoea Hypopnoea index		
Advice re air travel		
Ask about factors that help/hinder CPAP use		
CPAP unit noise level		
Nocturia/Frequency of getting up to pass urine		
Requirement to repeat diagnostic study with significant weight loss/weight gain		
Enquiring re possibility of other sleep disorders/i.e. restless leg syndrome		
Fatigue and depression scale /as interfering with epworth sleep score		
Requirement for humidification		
Frequency of cleaning mask interface and circuit/changing filters		
<p><b>Section 2 -Timing/frequency of CPAP review. This section is intended to gain consensus on how often a clinical review should take place. Please indicate by putting a cross in the final column your preferred timing for routine checks of a patient established on CPAP</b></p>		
Within 3-30 days after initial CPAP introduction		
Telephone reviews at 1,4,8 weeks following starting of trial		
3 monthly		
4 monthly		
6 monthly		
12-18 month review		
Every 2 years		
Every 5 years		
If poor compliance/usage seen every 6 months		
Follow up via -Telemonitoring where used		
On demand/open access review/based on patient need		
Forced review - ie request from traffic agency/pre planned surgery or similar		
Section 3 -	Additional free text comments	

On completion of your response please save to your desktop and return to me by email attachment to:  
s1470044@sms.ed.ac.uk

	<b>Round 3 - An International e-Delphi exercise to define the components of a clinical review of people using CPAP therapy</b>	Participant ID	
<p>There are three parts to this round of the study: (1) Scoring the importance of the components of a CPAP review, (2) specification of timing/frequency of CPAP review, and (3) opportunity to provide free text comments. We request that you complete sections 1 and 2 as a minimum.</p>			
<p>Thank you for agreeing to help with this e-Delphi exercise. <b>This is round 3.</b>  Listed below are the possible components of a clinical review of a patient using CPAP therapy. Column D gives the median score from all the participants of the e-Delphi; column E is your score from the previous round.  <b>Please review all the components listed below with their round 2 scores, and re-score the importance of the components in Column C (the shaded column) with 0 being unimportant and 5 being very important</b></p>			
Clinical CPAP review	We estimate it will take up to 15 mins to complete the round 3 questionnaire.		
Important!	Save this spreadsheet to your desktop, or a folder on your computer. If you don't do this you will lose all your responses when you close the spreadsheet		
<p><b>Section 1. Consists of components of a CPAP clinic review generated from round 1 of the e-Delphi study. Please specify the importance of these with 0 = unimportant and 5 = very important.</b></p>			
Component of the CPAP review	Round 3 score	Median score from round 2	Your score from round 2
Recording Epworth Sleep Score			
Verbally asking about CPAP adherence/Sleep time			
Recording of CPAP adherence/efficacy by data download via memory card/remote monitoring			
Checking mask fit issues			
Chest auscultation			
Checking for treatment side effects			
Checking electrical safety of CPAP unit			
Checking body weight			
Checking blood pressure			
Asking about current driving status - Car/Heavy goods Vehicle license			
Checking that any relevant Vehicle Licensing agencies are aware of the condition			
Review of medical history, medication, any new co morbidities in relation to symptoms/need for hospitalisation			
Checking partner feedback / quality of life			
Checking patient quality of life			
Checking patient physical activity/exercise			
Checking patient quality of sleep /feeling refreshed on waking			
Asking about quality/quantity of sleep/sleep routine times			
Asking about work schedule/Shift Pattern			
Ask if any problems with sleepiness while driving			
Checking if initial symptoms for referral have improved e.g. tiredness/sleepiness/hypersomnolence/ concentration/memory			
Patients preparedness to continue with treatment			
Check for control of witnessed residual snoring or apnoeas, choking spells			
Recording the altitude where the patient lives and the altitude where the sleep study was carried out			
Cognitive/developmental issues			
Support system at home (Help with mask on/off fitting and filling of humidifier if used) /partner engagement			
Examination of the nasal passage and throat			
Ensuring CPAP is resolving Apnoea Hypopnoea index			
Advice re air travel			
Ask about factors that help/hinder CPAP use			
CPAP unit noise level			
Nocturia/Frequency of getting up to pass urine			
Requirement to repeat diagnostic study with significant weight loss/weight gain			
Enquiring re possibility of other sleep disorders/i.e. restless leg syndrome			
Fatigue and depression scale /as interfering with epworth sleep score			
Requirement for humidification			
Frequency of cleaning mask interface and circuit/changing filters			
Section 2 - Timing/frequency of CPAP review. This section is intended to gain consensus on how often a clinical review should take place. Please indicate by putting a cross in the final column your preferred timing for routine checks of a patient established on CPAP	Round 3 selection	Number of participants selecting this	Your selection from round 2
Within 3-30 days after initial CPAP introduction			
Telephone reviews at 1,4,8 weeks following starting of trial			
3 monthly			
4 monthly			
6 monthly			
12-18 month review			
Every 2 years			
Every 5 years			
If poor compliance/usage seen every 6 months			
Follow up via -Telemonitoring where used			
On demand/open access review/based on patient need			
Forced review - ie request from traffic agency/pre planned surgery or similar			
Section 3 - Additional free text comments			
On completion of your response please save to your desktop and return to me by email attachment to: s1470044@sms.ed.ac.uk			